

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and
PEOPLE OF THE STATE OF NEW YORK,
by Letitia A. James, Attorney
General of the State of New York,

Plaintiffs,

- against -

QUINCY BIOSCIENCE HOLDING COMPANY,
INC., QUINCY BIOSCIENCE, LLC,
PREVAGEN, INC. d/b/a Sugar River
Supplements, QUINCY BIOSCIENCE
MANUFACTURING, LLC, and MARK
UNDERWOOD,

Defendants.

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 3/2/20

17 Civ. 124 (LLS)

OPINION & ORDER

Plaintiffs Federal Trade Commission ("FTC") and the People of the State of New York brought this action alleging violations of the FTC Act and New York law for deceptive advertising of a dietary supplement ("Prevagen") purporting to improve one's memory. Plaintiffs move to strike eight affirmative defenses from defendants' answers. For the following reasons, the motion is granted in part and denied in part.

BACKGROUND

Defendants Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC are wholly-owned subsidiaries of defendant Quincy Bioscience Holding Company, Inc. (collectively "Quincy"). Defendant Mark Underwood is the President and a co-founder of Quincy.

Plaintiffs brought this action alleging that defendants' advertisements falsely misrepresent that Prevagen improves memory and provides other cognitive benefits such as healthy brain function, a sharper mind, and clearer thinking.

On April 6, 2017, Defendants moved to dismiss the complaint on the following grounds: (1) the complaint fails adequately to allege that the advertisements' representations violate sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52; (2) the complaint fails adequately to allege that the representations violate section 63(12) of the New York Executive Law and sections 349 and 350 of the New York General Business Law; (3) the relief sought amounts to an unconstitutional restraint on commercial speech; (4) the action was commenced ultra vires as the FTC lacked a quorum to authorize it; (5) the court lacks personal jurisdiction over Mark Underwood and Michael Beaman; and (6) the complaint fails adequately to allege a claim for individual liability against Underwood and Beaman.

On September 28, 2017, the court dismissed the complaint for failure to state a claim under the FTC Act, declined to exercise supplemental jurisdiction over the New York law claims, and did not address defendants' other arguments. On April 15, 2019, the Second Circuit vacated that ruling and remanded to this court, stating "We note that Defendants-Appellees have raised several grounds for affirmance that the district court

did not consider. We express no opinion on these arguments, and the district court may consider them in the first instance on remand."

On July 24, 2019, the court ruled on the remaining issues of the FTC quorum, personal jurisdiction, and individual liability of Underwood and Beaman. The motion to dismiss the complaint was granted with respect to Beaman's individual liability, and denied in all other respects.

Quincy and Underwood filed their answers (Dkt. Nos. 73, 74) on August 7, 2019, asserting several affirmative defenses. Plaintiffs move to strike eight defenses.

DISCUSSION

Under Fed. R. Civ. P. 12(f), "The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter."

"In order to prevail on a motion to strike, a plaintiff must show that: (1) there is no question of fact which might allow the defense to succeed; (2) there is no question of law which might allow the defense to succeed; and (3) the plaintiff would be prejudiced by inclusion of the defense." S.E.C. v. McCaskey, 56 F. Supp. 2d 323, 326 (S.D.N.Y. 1999).

Failure to State a Claim Upon Which Relief Can Be Granted

Defendants' First Defenses are that the Complaint "fails to

state a claim upon which relief can be granted."¹

In its April 15, 2019 Summary Order, the Second Circuit held that "The FTC and New York have made plausible allegations that Quincy's marketing campaign for Prevagen contained deceptive representations," and "The FTC has stated a plausible claim that Quincy's representations about Prevagen are contradicted by the results of Quincy's clinical trial and are thus materially deceptive in violation of the FTC Act and New York General Business Law."

There is no need to litigate the same issue again, and the motion to strike the defense that plaintiffs fail to state a claim is granted.

Laches and Waiver

Quincy's Second and Underwood's Third Defenses state, "Plaintiffs' claims for relief are barred, in whole or in part, by the doctrines of laches and waiver."

"It is well settled that the United States is not bound by state statutes of limitation or subject to the defense of laches in enforcing its rights." United States v. Summerlin, 310 U.S. 414, 416, 60 S. Ct. 1019, 1020 (1940). The defense of "laches is not available against the federal government when it undertakes to enforce a public right or protect the public

¹ Defendants explain that this and some other defenses were claimed only to "preserve" them (for appeal). That is entirely unnecessary. Non-repetition of a wrongly lost point is not a waiver of the right to assert it on appeal.

interest." United States v. Angell, 292 F.3d 333, 338 (2d Cir. 2002).

Because the FTC brought this action to protect the public interest, there is no question of law or fact that would allow defendants to succeed on the defense of laches and waiver. Plaintiffs would be prejudiced by having to spend time and resources on litigating an invalid defense. See F.T.C. v. Consumer Health Benefits Ass'n, No. 10 Civ. 3551 (ILG), 2011 WL 13295634, at *6 (E.D.N.Y. Oct. 5, 2011) ("because laches is not an available defense against the FTC in an enforcement action such as this, there is no question of law or fact would allow Leo to succeed on this defense"); F.T.C. v. Instant Response Sys., LLC, No. 13 Civ. 00976 (ILG), 2014 WL 558688, at *2 (E.D.N.Y. Feb. 11, 2014) (granting motion to strike laches defense because "The FTC is seeking to enforce laws that protect the public and laches is not applicable."); F.T.C. v. Bronson Partners, LLC, No. 3:04CV1866 (SRU), 2006 WL 197357, at *2 (D. Conn. Jan. 25, 2006) (striking waiver defense because "The FTC's authority to bring an action under section 13(b) of the FTC Act is not derived from the defendants' contracts with individual consumers, and individual consumers' reliance on misrepresentations is not required," and "The FTC may not waive the requirement of an act of Congress."). The motion to strike the defense of laches and waiver is granted.

Validity of FTC Quorum

Quincy's Fifth and Underwood's Sixth Defenses state, "The FTC's filing of the Complaint constitutes an ultra vires act because it lacked a valid quorum of Commissioners to authorize its filing."

In its July 24, 2019 Opinion and Order, the court ruled that the three-Commissioner quorum was valid, and that the FTC's vote to bring this action was not ultra vires.

There is no need to litigate the same issue again, and the motion to strike the defense that the FTC lacked a valid quorum is granted.

Commercial Speech

Quincy's Sixth and Underwood's Seventh Defenses state, "The advertising claims challenged by Plaintiffs in the Complaint are protected by Quincy's right to commercial speech and are therefore immune from any regulation by the Government."

But deceptive commercial speech has no constitutional protection. As the Court of Appeals stated in Bristol-Myers Co. v. F.T.C., 738 F.2d 554, 562 (2d Cir. 1984),

Bristol argues that Part II violates the First Amendment in the light of the protection due commercial speech. See Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 96 S. Ct. 1817, 48 L.Ed.2d 346 (1976). See also In re RMJ, 455 U.S. 191, 207, 102 S. Ct. 929, 939, 71 L.Ed.2d 64 (1982). But, as we have pointed out, deceptive advertising enjoys no constitutional protection and it may be regulated, Jay Norris, 598 F.2d at 1251-52; see In re RMJ, 455 U.S. at 203, 102 S. Ct. at 937.

Since the purpose in the trial of this case is to determine whether or not the advertisement is deceptive, the motion to strike the defense is denied.

Good Faith

Defendants' Tenth Defenses state, "Defendants have acted in good faith in all aspects of their marketing and advertising practices, which prohibits Plaintiffs from obtaining any injunctive relief."

Defendants acknowledge that good faith is not relevant in determining whether they engaged in deceptive or fraudulent conduct. See F.T.C. v. Pharmtech Research, Inc., 576 F. Supp. 294, 301 (D.D.C. 1983) ("The advertiser's good faith or absence of intent to deceive is irrelevant.").

However, defendants' good faith is relevant to determining whether plaintiffs are entitled to a permanent injunction, which they seek. Although defendants' good faith in conducting clinical studies and advertising the results is not a defense to liability, it may be a viable defense to the granting of an injunction. See Bronson Partners, 2006 WL 197357, at *1:

Courts have held that good faith is not a defense for a violation of section 5 of the FTC Act. E.g., FTC v. World Travel Vacation Brokers, Inc., 861 F.2d 1020, 1029 (7th Cir. 1988). Nevertheless, if there has been a violation, the defendants' intent is relevant to the court's determination of appropriate relief. See FTC v. Medicor LLC, 2001 WL 765628, *2 (C.D. Cal. June 26, 2001) (denying motion to strike because good faith is relevant for determining whether to issue a permanent injunction and whether to hold defendants individually liable). Although the defendants' first affirmative defense does not

immunize them from liability, it may be relevant to the determination of appropriate relief. Thus, I deny the FTC's motion to strike the defense of good faith.

See also F.T.C. v. Nat'l Urological Grp., Inc., No. 1:04-CV-3294-CAP, 2005 WL 8155166, at *12 (N.D. Ga. June 24, 2005):

Should the court, however, determine that the defendants have violated § 5 of the Act, the court would have the option of granting permanent injunctive relief. 15 U.S.C. § 53(b)(2). As noted earlier in this opinion, injunctive relief is proper only when there exists some cognizable danger of recurrent violation. See Evans, 775 F.2d at 1087; see also Citigroup, Inc., 2001 WL 1763439 at *3. To determine whether a violation is likely to recur, the court may consider the deliberateness and seriousness of the violation, as well as the violator's own history of unfair advertising practices. Therefore, to the extent that good faith is offered as an affirmative defense to the violation of § 5 of the Act, it should be stricken. See Hang-Ups Art Enterprises, Inc., 1995 WL 914179, at *3, 1995 U.S. Dist. LEXIS 21444 at *10. To the extent that the good faith is offered against the granting of a permanent injunction against the defendants, it may be viable and should not be stricken at this stage.

Because the defense of good faith was timely filed, there is no prejudice to plaintiffs, and the motion to strike it is denied.

Primary Jurisdiction of FDA

Defendants' Thirteenth Defenses state, "Plaintiffs' claims fall within the primary jurisdiction of the Food and Drug Administration."

Under a memorandum of understanding between the FTC and FDA, "the FTC has generally taken the enforcement lead where the false or misleading claims for dietary supplements appear predominantly in advertising, and the FDA has generally taken the lead where such claims are limited to labeling." Pls. Br.

at 10. Because "This action is brought against Defendants in connection with the labeling, advertising, marketing, promotion, distribution, and sale of Prevacid," Compl. ¶ 2, defendants argue that plaintiffs' claims are under the FDA's jurisdiction.

The FTC's authority to bring this action is not limited by the FDA's jurisdiction over claims related to labeling. In response to an argument that "the FDA should be allowed exclusive regulatory authority over the marketing and labelling of OTC drugs while its review is pending," the D.C. Circuit stated in Thompson Med. Co. v. F.T.C., 791 F.2d 189, 192-93 (D.C. Cir. 1986),

It strains credulity to argue that even the most blatantly false or deceptive advertising of OTC drugs must be allowed so long as the FDA is evaluating the efficacy of those drugs.

We find no evidence in the regulatory scheme that Congress has fashioned for over-the-counter medications that the FTC is indefinitely barred from all regulatory authority over drug advertising while the FDA conducts its comprehensive review of drug safety. Nowhere in the case law or in the FTC's grant of authority is there even a hint that the FTC's jurisdiction is so constricted. To the contrary, the cases recognize that ours is an age of overlapping and concurring regulatory jurisdiction. See Federal Trade Commission v. Texaco, Inc., 555 F.2d 862, 881 (D.C. Cir.), cert. denied, 431 U.S. 974, 97 S. Ct. 2940, 53 L.Ed.2d 1072 (1977) ("this is an era of overlapping agency jurisdiction under different statutory mandates"). In an analogous context the Supreme Court held that the FTC's jurisdiction is concurrent with that of the Attorney General to file an antitrust suit. See Federal Trade Commission v. Cement Institute, 333 U.S. 683, 694-95, 68 S. Ct. 793, 800-01, 92 L.Ed. 1010 (1948). Other agencies and their mandates similarly overlap; not even a faint clue exists that Congress desired otherwise.

The FTC has substantial expertise in evaluating claims of drugs' absolute and comparative efficacy, and in assessing whether

advertisements are misleading or deceptive. See, e.g., Warner-Lambert Co. v. Federal Trade Commission, 562 F.2d 749, 753-56 (D.C. Cir. 1977), cert. denied, 435 U.S. 950, 98 S. Ct. 1576, 55 L.Ed.2d 800 (1978); American Home Products Corp. v. Federal Trade Commission, 695 F.2d 681, 691-93 (3d Cir. 1982). We see no reason why the FTC should not be allowed to exercise that expertise in the circumstances presented here.

The court in Thompson Med. also quoted Bristol-Myers Co. v. F.T.C., 738 F.2d 554, 559 (2d Cir. 1984), which stated,

Insofar as FDA requirements and regulations are concerned, they simply do not govern this case. Not only is a different regulatory scheme involved, but generally speaking the FDA is concerned only with evaluating absolute safety and efficacy, and not with the questions of comparative safety and efficacy that arise in OTC drug advertising.

Given the two agencies' "overlapping and concurring regulatory jurisdiction," the FDA's supposed "primary jurisdiction" is not a viable defense to plaintiffs' claims. The motion to strike it is granted.

NYGBL Claims

Defendants' Fifteenth Defenses state, "The alleged conduct complained of in the Complaint involves transactions or acts that took place outside of New York. As a result, the claims under New York General Business Law §§ 349 and 350 fail."

Plaintiffs argue that the court's July 24, 2019 Opinion and Order rejected that defense when it found that there was personal jurisdiction over Underwood and Beaman with respect to both the FTC Act and New York law claims. However, that ruling was based on the FTC Act's authorization of nationwide service and nationwide personal jurisdiction, and the finding that

Underwood and Beaman had sufficient minimum contacts with the United States. The Opinion and Order did not address whether defendants had sufficient contacts with New York, or whether any deceptive conduct occurred in New York.

New York General Business Law ("NYGBL") §§ 349 and 350 prohibit deceptive acts or practices and false advertising "in the conduct of any business, trade or commerce or in the furnishing of any service in this state." At this stage in this case it is undetermined whether any deceptive conduct occurred in New York; if not, the defense might prevail.

The facts will have to be ascertained in the resolution of plaintiffs' own NYGBL claims, and the motion to strike the defense that deceptive conduct only occurred outside New York is denied.

Right to Raise Additional Defenses

Quincy's Seventeenth Defense and Underwood's Preamble to Defenses reserve "the right to raise additional affirmative and/or other defenses as may be established by discovery and other evidence developed during the pendency of this action."

If defendants seek to raise other defenses during the pendency of this action, they may do so "with the opposing party's written consent or the court's leave" under Fed. R. Civ. P. 15(a). The motion to strike defendants' reservation of an untrammelled right to raise additional defenses is granted. See

Nat'l Urological Grp., 2005 WL 8155166, at *12 (striking "reservation of rights" defense because under Fed. R. Civ. P. 12(b), "absent permission of the court, the defendants are required to assert every defense in their answer"); Cty. Vanlines Inc. v. Experian Info. Sols., Inc., 205 F.R.D. 148, 157-58 (S.D.N.Y. 2002) (alterations in original):

In Boss Prods. Corp. v. Tapco Int'l Corp., No. 00 Civ. 0689, 2001 WL 135819, at *3 (W.D.N.Y. Feb.16, 2001), the court struck the defendant's affirmative defense that sought to reserve "the right to add additional Affirmative Defenses as discovery proceeds in this case." The court reasoned that "[i]f, by the inclusion of such defense, defendant wishes to reserve the unilateral right to add new and different affirmative defenses as they become known to it at indeterminate times in the future, any such addition would violate, inter alia, the fair notice requirement of [Fed. R. Civ. P. 8] and circumvent [Fed. R. Civ. P. 15.]" Id. We agree. Should any facts arise during discovery that support any additional defenses, the proper avenue by which defendant can and should proceed is detailed in FED. R. CIV. P. 15(a). Accordingly, plaintiff's motion to strike defendant's sixteenth affirmative defense is granted.

CONCLUSION

Plaintiffs' motion to strike defendants' affirmative defenses (Dkt. No. 86) is granted in part and denied in part. The motion to strike the defenses of failure to state a claim (Defendants' First Defenses), laches and waiver (Quincy's Second and Underwood's Third Defenses), validity of the FTC quorum (Quincy's Fifth and Underwood's Sixth Defenses), primary jurisdiction of the FDA (Defendants' Thirteenth Defenses), and the right to raise additional defenses (Quincy's Seventeenth Defense and Underwood's Preamble to Defenses) is granted. The

motion to strike the defenses of protected commercial speech (Quincy's Sixth and Underwood's Seventh Defenses), good faith (Defendants' Tenth Defenses), and NYGBL claims (Defendants' Fifteenth Defenses) is denied.

Defendants' request for leave to file an amended answer with additional factual allegations is denied because amendment of the stricken defenses would be futile.

So ordered.

Dated: New York, New York
March 2, 2020

Louis L. Stanton

LOUIS L. STANTON
U.S.D.J.